

REMARKS/ARGUMENTS

Claims 1, 4, 8-10, and 13 were amended. Claims 2, 3, 6, 11 and 14 were canceled. Claims 5, 7, 12 and 15 are unchanged. The claims pending after this amendment are 1, 4-5, 7-10, 12, 13 and 15. Support for the amendments can be found on page 6, lines 9 to 12 and canceled claim 6.

Claim Objections

Claims 8-9 were objected to under 37 CFR 1.75(c) as improper multiply dependent claims. As currently amended, neither claim is multiply dependent; therefore this objection is no longer relevant. Both amended claims 8 and 9 now depend only on claim 1.

Claim Rejections – 35 USC § 102

Claims 1-7 were rejected under 35 U.S.C. 102(b) as being anticipated by Bartz et al. The Bartz et al. reference calls for an amino acids mixture employing a number of amino acids. The composition of the present invention utilizes only one amino acid, namely taurine. Taurine is only one out of 11 amino acids used in the amino acid mixture described in the Bartz et al. reference. Example 1, on pages 10-11 of the Bartz et al reference, discloses adding 4.9 g/L of taurine to one liter of water, but Bartz et al. calls for 10 other amino acids. The total amount of amino acids is 76.3 g/L. This 11 amino acid mixture is further diluted to a final concentration of 10 g/L amino acids, and then this 10 g/L of the diluted amino acids mixture solution is used for preparing the solution for intraperitoneal administration of Bartz et al.

Accordingly, the final concentration of taurine in the solution for intraperitoneal administration of Bartz et al. is about 0.64 g/L (=0.064 w/v%), and other amino acids, such as L-histidine, L-isoleucine, L-leucine, etc. are essential components of the solution for intraperitoneal administration of Bartz et al. In contrast, the amount of taurine as claimed in the present application is 0.1 to 3.5

w/v%, and no other amino acids are necessary for the peritoneal dialysate of the present invention.

Claim Rejections – 35 USC § 103

Claims 10-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bartz et al. Applicants respectfully submit that one of ordinary skill in the art would not be motivated to make the composition of the present application from the Bartz et al. disclosure. There is no reason why one skilled in the art would drop the other 10 amino acids which form an essential part of the composition described in the Bartz et al. reference. The amino acids in Bartz et al. are included as nutrients. As noted on page 8, first paragraph of Bartz et al.:

BARTZ ET AL.

“According to the invention it has been surprisingly found that when using the amino acid mixture set forth above it is possible when treating kidney-deficient patients to make an effective nutritive contribution. The composition of the amino acid according to the invention is adapted to the needs of the kidney-deficient patient. The basis of the composition of the amino acid mixture according to the invention is not the plasma amino acid pattern but the amino acid pattern of intracellular relevant amino acid pools (muscles).”
(Emphasis added.)

Taurine serves a completely different purpose in the present invention. Taurine, and no other amino acid, “is added to a peritoneal dialysate to serve as an osmotic agent.” See page 5, lines 29-31 of the present application. Taurine is an osmotic agent not a nutrient. Taurine’s other functions and advantages in the present invention include:

DISCLOSURE OF PRESENT INVENTION

“Taurine, an amphoteric ion, exhibit a neutral pH when dissolved in water and has the ability to buffer pH changes. For this reason, taurine can be used to stabilize the pH of peritoneal dialysates during sterilization and storage.”
Page 5, lines 31-34 of the present application.

The pH range of 6.0 to 7.5, and the particular concentration of 25 to 45 mEq/L of sodium lactate of the present invention are achieved by using taurine as the osmotic agent. There is no rationale that would motivate one to modify the 11 amino acids mixture of Bartz et al., meant to mimic and provide the nutritive needs of muscle tissue, by dropping 10 other amino acids in order to create the osmotic and stabilizing agent of the present invention. Applicants respectively submit that claims 10-13 and 15 are unobvious in view of the Bartz et al. reference and that the pending claims are allowable as amended.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

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